REMARKS

Applicants respond to the Examiner's detailed June 9, 2009 Office Action with the following remarks presented according to the Examiner's communication. Claims 14, 16 – 22 and 24 – 55 are pending, and are rejected. Claims 18, 36, and 55 are herewith cancelled. Claims 16, 29, 30, 32, 33, 37, and 44 are currently amended. Support for this amendment can be found throughout the specification, and in the original claims. No new matter is presented by the amendment. Accordingly, applicants respectfully request entry of the amendment, and reconsideration of claims 14, 16 – 17, 19 – 22, 24 – 35, and 37 – 54 in light of the following remarks.

Claim Objections

Claims 36 and 55 are objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 36 and 55 are herewith cancelled. Accordingly, Applicants respectfully request the Examiner reconsider and withdraw this objection.

Rejections under 35 USC § 103

Claims 16 – 17, 24, 28 – 32, 34, 35, 37, 40 – 42, 47, and 52 were rejected as allegedly being obvious over U.S. Patent No. 4,440,877 ("Hauschild"). Applicants respectfully traverse the rejection for the following reasons.

The test that must be met for a reference or a combination of references to establish obviousness has also not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and

determination of obviousness under 35 U.S.C. 103 ...

[T]he four factual inquires enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141)

When applying 35 U.S.C. § 103(a), the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined (MPEP § 2141). None of these criteria have been met here.

First, Hauschild fails to disclose the limitations of independent claims 16 and 37 reciting, e.g., a dentrifice having flakes formed from a water hydratable film matrix wherein the water soluble film matrix comprising a mixture of a water soluble hydroxyalkyl methyl cellulose polymer and a starch, wherein the ratio of hydroxyalkyl methyl cellulose polymer to the starch is about 1:3 to about 4:1, wherein the flakes contain a constituent. More particularly, Hauschild does not teach a dentifrice having <u>flakes</u> formed from a water hydratable film matrix. Nor does Hauschild teach a water soluble film matrix comprising a mixture of <u>a water soluble hydroxyalkyl methyl cellulose</u> <u>polymer and a starch</u>, wherein the ratio of hydroxyalkyl methyl cellulose polymer to the starch is about 1:3 to about 4:1, wherein the flakes contain a constituent.

Second, Hauschild explicitly teaches away from the claimed composition comprising methyl cellulose. A reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). When read as a whole, Hauschild teaches very specific agglomerate speckles containing a mixture of water insoluble, ethanol soluble, ethyl cellulose and polyvinyl pyrroidone (PVP). (See Hauschild, Col. 2, Il. 25 – 30, emphasis added.) In contrast, the presently-claimed invention requires a mixture of a water-soluble hydroxyalkyl methyl cellulose polymer and a starch. Hauschild, however, teaches that mixtures comprising methyl cellulose "are water soluble and therefore do not provide a speckle which will always sufficiently and easily maintain its integrity during lengthy processing." (Col. 1, Il. 62-67, emphasis added.) Hauschild goes on to disparage the use of methyl cellulose at length:

...speckles, made with water soluble binders, such as, methyl cellulose or PVP, could disintegrate during processing after mixing in with other dentifrice components, such, as those in previously formulated gel or paste media, if the speckled dentifrice was held too long in the processing equipment, which can happen, as when mechanical breakdowns of processing equipment occur. Such losses of integrity of the speckles could take place because such dentifrices contain water, which can solubilize the water soluble binders of the speckles and lead to separation of the component particles of the speckles, and also eventually soften to an impalpable unit on storage in a dentifrice.

(Col. 2, lines 25-41, emphasis added.) Therefore, the skilled artisan would understand Hauschild to teach that using water-soluble methyl cellulose, as opposed to water-insoluble ethyl cellulose as claimed, is highly undesirable.

The Office Action points to Example 6 of Hauschild as allegedly teaching that

...hydroxypropyl methyl cellulose is used in making speckles and carboxymethyl cellulose (CMC), which is disclosed as being a suitable water soluble polymer for using [sic] in combination with ethyl cellulose, is used as well...HPMC was shown to yield better results than CMC and therefore it would be reasonable for one of ordinary skill in the art to use HPMC as the water soluble polymer in combination with ethyl cellulose...

(Office Action at 4.) Applicants have examined this portion of Hauschild but can find no support for this allegation. In fact, Hauschild explicitly teaches away from the use of water soluble methyl cellulous in this example and elsewhere. In particular, Hauschild states:

Speckles of various compositions are compared to those of this invention that are based on ethyl cellulose and PVP... When 2% of sodium carboxymethyl cellulose is employed as the binder the speckles lose integrity within fifteen seconds, which is also the case with the speckles bound with 2% of hydroxypropyl methyl cellulose, but that takes two minutes. Speckles made with a binder comprising 2% of methyl cellulose and 3% of PVP soften, swell and lose integrity after about two minutes and when 5% of PVP is employed as the sole binder speckles made with it soften after eight minutes. When the binder is 1% of methyl cellulose (400 centipoises) the speckles lose integrity after a little more than five minutes and when the binder is changed to 10% of polyethylene glycol 6,000, with 1% of magnesium stearate, with the speckles being made by "slugging"; they lose integrity after nineteen minutes. The "control" speckles of this invention, including 2% of ethyl cellulose and 3% of PVP, when, subjected to the same test, are still intact after over six hours.

(Col. 17, l. 49 – Col. 18, l. 14.) Thus, in the context of Example 6, Hauschild extols the benefits of using water-insoluble ethyl cellulose over methyl cellulose. (*See* Col. 18, ll. 15-18, "The results of this test <u>clearly indicate the importance of the presence of ethyl</u> <u>cellulose</u> with a water soluble binder, preferably with PVP," emphasis added.)

Because Hauschild teaches the requirement of ethyl cellulose, rather than methyl cellulose, the skilled artisan would have no reasonable expectation of success in arriving at the presently-claimed invention. Moreover, Hauschild's repeated disparagement of methyl cellulous highlights a fundamental distinction between Hauschild and the present application. Accordingly, Applicants therefore submit that Hauschild does not render obvious the present claims, as amended, and respectfully request reconsideration and withdrawal of the rejection.

Claims 14, 20 – 22, 25 – 27, 38, 39 and 43 – 54 were rejected as allegedly being obvious over Hauschild in view of U.S. Patent Application Publication No. 2002/0187108 (Rajaiah). Applicants respectfully traverse the rejection for the following reasons.

The rejection is based on Hauschild, for the same reasoning as set forth for the rejection based on Hauschild alone. The Rajaiah reference does not remedy the deficiencies of Hauschild. That is, Rajaiah, when read as a whole, does not teach that a composition as taught by Hauschild could be successfully prepared without using ethyl cellulose. In particular, Rajaiah does not provide any teaching or suggestion that the claimed composition comprising methyl cellulose could be successfully used.

Accordingly, Applicants submit that Hauschild and Rajaiah, when viewed together, do not provide the requisite teaching, suggestion, or motivation to arrive at Applicants' presently-claimed invention. Therefore, Applicants respectfully submit that the references therefore do not render obvious claims 14, 20 – 22, 25 – 27, 38, 39 and 43 – 54, and request reconsideration and withdrawal of the rejection.

SUMMARY

Applicants believe that the pending claims are in condition for allowance and favorable consideration is solicited. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

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